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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
PORTNER, V	
ART UNIT	PAPER NUMBER
1645	31

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/837,459	McKee et al
Examiner	**Art Unit**
Portner	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 19, 2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *60 and 66-90* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *60 and 66-90* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 30
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claim 60 has been amended.

Claims 64 and 65 have been canceled.

New Claims 66-90 have been submitted.

Claims 60, 66-90 are under consideration.

Continued Prosecution Application

1. The request filed on March 19, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/837,459 is acceptable and a CPA has been established. An action on the CPA follows.

Priority

2. This application repeats a substantial portion of prior Application Nos 60/015,657 and 60/015,936 filed (4/19/96) and (4/22/96), respectively, and adds and claims additional disclosure not presented in the prior application (see page 47, which references a November 1996 article).. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Please Note: Claim 60 has been amended to recite the step of "generating anti-intimin antibodies", wherein the anti-intimin antibodies are defined as a product obtained by the recited process, but could be produced by a different process that produces the same or equivalent product which is then administered to a patient. The process step of generating antibodies to enriched or purified intimin protein defines a single process for obtaining the recited "anti-intimin antibodies" and any process that would produce the same or equivalent product of anti-intimin antibodies would meet the recited methods step of generating anti-intimin antibodies.

All of the claims recite open language "comprising , the level of purity for intimin is not defined and encompasses any level of purity, the term "enriched" also encompasses any level of purity and the antibodies generated may be polyclonal or monoclonal antibodies.

Rejections Withdrawn

3. Claim 65 rejected under 35 U.S.C. 102(b) as being anticipated by Cravioto et al (1991), because the claim has been canceled.

4. Claim 64 rejected under 35 U.S.C. 103(a) as being unpatentable over Dougan et al (US Pat. 5,747,293), because the claim has been canceled.

Please Note: the phrase "domesticated animal" is being read to include humans.

Rejections Maintained

Please Note: In view of the claims not reciting a specific type, specificity or concentration of antibodies generated, nor any *specific* amount of antibodies in the administering step, the following rejections are being maintained in view of the references generating antibodies that would specifically bind to intimin, and the antibodies administered had or would have the functional limitations for the antibodies recited in the claims.

5. Claims 60, 66, 71, 76, 87 (being read to include oral ingestion of food or water containing intimin for generating anti-intimin antibodies) rejected under 35 U.S.C. 102(b) as being anticipated by Cravioto et al (1991) as applied to claim 60, for reasons of record in paper number 27, paragraph 1 and because the term "enriched" is being viewed to include enriched expression of intimin by the pathogen under disease producing conditions, which results in generating "anti-intimin antibodies".

6. Claim 60,66-67, 76,77, 83-84, 85-86, 89,90 rejected under 35 U.S.C. 103(a) as being unpatentable over Dougan et al (US Pat. 5,747,293), as applied to claim 60, for reasons of record in paper 27, paragraph 5 .

Response to Arguments

7. Applicant argues the rejection of claims 60, 66, 71, 76, 87 under 35 U.S.C. 102(b) as anticipated by Cravioto et al (1991)) by stating:

a. Cravioto et al "fails to teach generating anti-intimin antibodies through the administration of enriched or purified intimin protein to a host";

b. Asserts that the method of Cravioto "requires an infection with pathogenic bacteria, and would thus not be useful for methods of preventing infection" and

c.states that the instant method "does not require infection with dangerous bacteria"

8. Applicant's arguments filed with respect to Cravioto et al (1991) have been fully considered but they are not persuasive because:

a. The method step "generating anti-intimin antibodies" is taught in Cravioto, wherein the immune system of the host was stimulated with intimin ((see narrative for Figure 6 and Figure 6, page 1251) and resulted in generating anti-intimin antibodies to the enriched, expressed levels of the virulence factor upon exposure of the mother's immune system to the antigen producing pathogen.

The generated polyclonal antibodies were found to evidence passive immune protection against infection in vivo in the patients to whom the antibodies were administered. The protective effect is protection from infection caused by E.coli strains that produce the attaching and effacing lesion mediated by intimin. Cravioto et al referred to intimin as the "adherence factor" (see abstract). Agin et al, reference of record, quotes Cravioto as showing that sIgA isolated from

human breast milk, blocks adherence of EPEC to Hep-2 mammalian cells (see Agin, page 318, paragraph 2) and that sIgA in breast milk recognized EPEC intimin (see page 318, first full paragraph lines 3-5). Agin also teaches that intimin is the bacterial protein that is required in the formation of attaching and effacing lesions characteristic of EPEC and EHEC infections in humans (Agin, abstract, first three lines). Protective polyclonal antibodies that are anti-intimin antibodies that are protective in EPEC would also inhibit binding of EHEC to mammalian cells. Inherently the anti-intimin polyclonal antibodies administered protected against the family of attaching and effacing lesion inducing pathogens, enterohemorrhagic E.coli strains of bacteria are included in this family.

Cravioto et al disclose a method of providing passive immune protection comprising generating anti-intimin antibodies, and administering an amount of isolated anti-intimin antibodies effective to provide passive immune protection to a patient in need thereof and anticipates the now claimed invention.

b. With respect to the differences in the method of the instant Application and that of Cravioto for generating anti-intimin antibodies, it is the position of the examiner that the instantly claimed invention recites open language thus permitting additional methods steps as disclosed by Cravioto.

c. With respect to argument made that Cravioto's method requiring infection and the instantly claimed invention does not, the examiner points to the specification, page 6, lines 3-7, that use of Salmonella and Shigella as means for "infecting the gastrointestinal tissue" . Thus

Applicant's specification teaches the use of live vaccine vectors for "generating anti-intimin antibodies". Applicant's arguments are not commensurate in scope with the claimed invention that permits the generation of anti-intimin antibodies through infection of the gastrointestinal tract.

9. The rejection of claims under 35 U.S.C. 103(a) as being unpatentable over Dougan et al (US Pat. 5,747,293) is argued by asserting:

a. that the instant invention has "found commercial success" through being subject to a license.

b. The Dean-Nystrom Abstract is cited to show the "efficacy of the use of intimin in a passive immunity model system, as proposed by the inventors at the time of filing." The data presented in this abstract show actual results providing passive immune protection."

10. Applicant's arguments filed with respect to commercial success and a showing of data for passive immune protection relative to the application of Dougan have been fully considered but they are not persuasive because:

a. while attainment of a licence is means for commercialization of a product, it does not establish the product as evidencing commercial success as a product.

b. With respect to the abstract submitted, and the assertion that the claimed invention is both novel and unobvious, it is the position of the examiner that the data presented is not commensurate in scope with the claimed invention. The claimed invention is not limited to

patients that are nursing farm animals, nor is it a method of producing a safer food source. The claimed method(s) are directed to providing passive immune protection to any patient, with anti-intimin antibodies obtained from any source, of any concentration, of any dose size (claims 60 and 76).

The Dean-Nystrom Abstract obtained the antibodies administered to the piglets through an immunization process that vaccinated the host twice (see abstract, line 10). The antibodies were administered in colostrum, with titers of greater than or equal to 100,000. The claimed invention does not recite the limitations of first and second vaccinating step, the antibodies are not limited only to colostral antibodies (claims 60, 66-73, 75-90 do not recite the limitation of colostrum), and no claims require any specific titer or concentration. With respect to claim 74, which recites that administering the amount of generated anti-intimin antibodies directly from the pregnant animal to its offspring, the type of antibodies are not defined to be colostral antibodies and could be placental immunoglobulins passed directly from the pregnant animal to the offspring. The amount of generated antibodies administered is not defined by titer, by length time of suckling nor limited to a pregnant pig. The results shown in the abstract ~~that~~ are not commensurate in scope with the claimed invention.

Claim Rejections - 35 U.S.C. § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> ***The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to***

> ***enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.***

12. Claims 72-73, 75, 78-79, 82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 72-73, 75, 78, 82 recite the method step of "butchering". No original descriptive support for butchering an animal could be found. Upon consideration of the discussion provided by Applicant, and teachings of the specification, the examiner could not find original descriptive support for butchering of the passively immunized animals. A discussion of "the subjective nature of differentiating between cooked and uncooked hamburger, a convenient stop at a fast food restaurant or even a family barbecue (page 2, third paragraph)", does not provide original descriptive support for the claimed methods step of butchering passively immunized animals. The recited claim limitations constitute New Matter.

Claim 79 recites the method step of "breeding said at least one animal". Where in the specification the method of passively immunizing an animal is taught to include breeding the animal could not be found. Original descriptive support for this method step was not found and constitutes New Matter.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 66, 68-75, 78-79 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 66 defines the host to be an animal that is a "wildlife". What wildlife animals would be available to be a host for generating anti-intimin antibodies, with subsequent administering of the antibodies to a patient, in a method of providing passive immune protection and is not a domesticated animal ?

Claim 68 defines the host animal to be a "nursing animal". Nursing animals are generally understood to be immature immunologically for a period of time after birth. How can a nursing animal be the host animal for generating anti-intimin antibodies if the immune system is not able to generate antibodies? Clarification of the nursing animal defined to be the host is requested.

Claim 69 defines the patient as "an offspring" of "a nursing animal". A nursing animal is understood to be immature biologically and unable to reproduce. How can a nursing animal have an offspring?

Claim 70 recites that the patient is an animal and a newborn. If the patient in claim 60 is not an animal, what is it? Stedman's Medical Dictionary, defines patient to be " One who is suffering from any disease and is under treatment for it." Is Applicant considering cultured cells

to be a patient?. In light of the claim limitations recited in claim 70, clarification of the definition of what the "patient" is, is requested.

Claim 72 depends from claims 70 and 67 and defines the method step of butchering the animal. The definition of "butcher" in Webster's Dictionary is defined as "to slaughter or prepare for market; to kill brutally or pointlessly". Why would you butcher a mouse? The invention for passive immunization of a patient is for conferring protection against infection, not killing the animal. The invention is not distinctly claimed.

Claim 73 depends from claim 66 and defines the methods step of butchering the animal. Why would you butcher a domestic animal (dogs, cats, pets, humans) or laboratory animal for food? The invention is directed to providing passive immunization to a patient not killing the animal. The invention is not distinctly claimed.

Claim 74 defines the administering of the generated anti-intimin antibodies directly from the pregnant animal to the offspring before birth, in view of claim 75. This process is a process that is carried out in nature, passage of antibodies across the placenta to the offspring. The antibodies of claim 74 pass directly from the pregnant animal to the offspring in utero. How do you know what antibodies were administered directly ? How do you know the amount administered is effective to protect the offspring against infection? Applicant can not claim a product of nature. Clarification is requested of the meaning of the term "directly" in view of the offspring not having been born yet, which is defined in claim 75. Clarification of the method of passive immunization being carried out is requested

Claim 75 defines an additional step of "birthing said offspring, and butchering at least one of said offspring and said host animal." If the offspring is immediately butchered, then when is it passively immunized? How many offspring were born to the host animal because the claim recites the phrase "at least one"? Claim 74 recites the term "offspring" in the singular and claim 75 defines the offspring in the plural and depends from claim 74. The plural term does not evidence antecedent basis in the claim from which it depends. How do you know that the amount of antibodies administered was effective to prevent infection if the offspring is immediately butchered?

Claim 75 also recites the step of butchering the host animal. How can the anti-intimin antibodies be directly administered from the host to the offspring by way of nursing if the host is butchered?

Claim 78 depends from claim 76 and defines the method step of butchering the animal. Why would you butcher a laboratory animal for food? Why would you butcher a domestic animal (dogs, cats, pets, humans), laboratory animal or wildlife after passively immunizing to protect it? The invention is directed to providing passive immunization to a patient not killing the patient. The invention is not distinctly claimed.

Claim 78 recites the phrase "said at least one animal" and depends from claim 77. Claim 77 does not provide antecedent basis for this phrase.

Claim 79 recites that additional methods step of breeding the "cow, pig, rabbit or mouse". How does this method step correlate with the preamble of the claim that is directed to a method

of providing protection of enterohemmorrhagic E.coli infection? What does breeding have to do with passive immune protection from infection? The method step does not correlate or relate to the claimed method of protecting an animal.

Claim 79 recites the phrase "said at least one animal" and depends from claim 77. Claim 77 does not provide antecedent basis for this phrase.

Claim 82 recites the additional methods step of butchering the cow or calf. How does this method step correlate with passive immunization of the animal? The additional step does not correlate with the preamble of the claimed method. Is the intended method, a method of producing a safer food supply? If this is what is intended, it is not claimed.

New Claim Limitations/ New Grounds of Rejection

Claim Rejections - 35 U.S.C. § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 60, 66-71, 74, 76-77, 80-81, 83-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Childlow et al (US Pat. 4,141,970) in view of Cravioto et al (1991).

The claimed invention is directed to a method of passively protecting a patient from infection through generating and administering anti-intimin antibodies to a patient. The antibodies are generated in a host, wherein the host can be a pregnant animal and the patient the off-spring. Antibodies are generated by either oral or parenteral administration of antigen to the host. The administration of the antibodies is accomplished by direct administration from the host to the patient through milk or colostrum.

Childlow et al teach a method of enhancing resistance of a new born mammal to gastro-intestinal infection (title), to include E.coli O157 (see '970, claims 6 and 8), wherein the method comprises the steps of:

generating antibodies in a host (see col. 1, lines 60-61) to an appropriate antigenic material (see col. 1, line 56; col. 4, lines 40-41; col. 2, lines 67-68- col. 3, lines 1-3);

administering the antibodies in an effective amount to provide passive immune protection in the patient (col. 1, line 63) to prevent infection from E.coli O157(col. 3, lines 8-23) and other pathogenic strains of E.coli (see claims 6-8).

The generating of antibodies is accomplished by parenteral injection or oral administration (see col. 3, line 24). Intravenous injection of antigen to generate antibodies in rabbits was taught (see col. 7, line 19). Ingestion of food containing the antigen for generating antibodies was also shown (see col. 4, line 43).

The animals include mammals that are pigs, cows and sheep (see col. 2, line 29). The host is a pregnant animal or mother (see '970, col. 3, lines 48-61, col.1, line 58) and the patient the

newborn offspring (see '970, col. 1, line 63). The direct administering of antibodies is through the suckling of the newborn offspring (see col. 5, lines 18-20) or through the placenta (col.1, line 61).

The pregnant animal is immunized prior to birth to insure a high titer colostrum (see col. 4, line 65) and milk (col. 4, line 67), wherein the antibodies are effective to decrease the number of pathogens excreted into the outside environment (see '970, col. 3, lines 50-61) and provide passive immune protection of the patient (see col. 6, lines 7-11).

Childlow et al differs from the instantly claimed invention by failing to teach the generated antibodies included anti-intimin antibodies, or to use purified intimin in generating anti-intimin antibodies in a method of providing passive protection against infection, wherein the anti-intimin antibodies block binding to a mammalian cell.

Cravioto et al teach anti-intimin (E.coli 94 kDa, adherence factor) antibodies that were able to block binding to mammalian cells in vitro (see page 1249, inhibition assays), showed generated anti-intimin antibodies administered from a mother to a newborn child provided passive immune protection against infection (see page 1247, col. 1, first sentence) and showed the intimin antigen to be immunoreactive with protective antibodies, wherein the intimin was purified by gel electrophoresis (page 1251, Figure 6, and narrative) in an analogous art for the purpose of defining the antigen that generated protective antibodies against pathogenic E.coli and to show that the generated antibodies could block. binding of the pathogen to mammalian cells.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the method of Childlow et al with the purified antigen of Cravioto, because Cravioto showed anti-intimin antibodies to function to block binding of E.coli to mammalian cells (page 1249, col. 1-2, inhibition assays) and upon administering the antibodies to a patient resulted in passive immune protection against infection (page 1247, col. 1, first sentence).

Childlow teaches the importance of inducing enhanced passive immune protection in an offspring through increasing of colostrum and milk titers to specific pathogen antigens (col. 4, lines 17-21) through injection or ingestion of antigen (see col. 1, lines 55-56) by the host, followed by administration of the generated antibodies to the patient. The person of ordinary skill in the art would have been motivated by the reasonable expectation of success for providing passive immune protection to a patient through ~~generate~~ anti-intimin antibodies using purified intimin as taught by Cravioto, in the method of Childlow because Cravioto teaches that colostrum antibodies directed to intimin were antibodies that correlated with protection of infants against infection and Childlow is interested in generating antibodies that are able to block binding to mammalian cells to prevent infection (col. 4, line 20-21).

In the absence of a showing of unexpected results, Childlow in view of Cravioto obviates the now claimed invention.

17. Claims 60, 66-71,74, 76-77, 80-81, 83-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dougan in view of Childlow et al (US Pat. 4,141,970).

The claimed invention is directed to a method of providing passive immune protection against enterohemorrhagic E.coli, wherein anti-intimin antibodies are generated to purified intimin and then administered to a patient in need thereof, wherein the patient is a cow, a pig, or domestic animal, the host is a mother and the administered anti-intimin antibodies are in colostrum or milk.

Dougan teach a method of generating anti-intimin polyclonal and monoclonal antibodies (see col. 2, line 53 and col. 2, lines 47-52) using purified intimin from enterohemorrhagic E.coli (see col. 4, lines 6-7 (first full sentence)), in one embodiment the generated anti-intimin antibodies were induced to a composition that comprises an adjuvant and teaches the administration of antibodies for passive immune protection against infection caused by E.coli (see col. 2, line 43 and col. 1, lines 8-11). EHEC and EPEC, both produce intimin, and share conserved antigenic sequences at the carboxy terminal that mediate attachment to patient cell receptors (col. 2, lines 9-13). Dougan teaches generation of anti-intimin antibodies to the domain of intimin that mediates attachment to mammalian cells, wherein the antibodies were block binding.

Dougan shows the generation of anti-intimin antibodies and suggests the administration of the antibodies to provide passive immune protection against enterohemorrhagic E.coli infection, but differs from the instantly claimed invention by failing to show the generation of the antibodies

in a host and administration of the antibodies from the host to an offspring in the form of colostrum or milk.

Childlow et al teach a method of generating anti-E.coli O157 antibodies in a host through parenteral, intravenous or oral immunization, and administration of the antibodies from the host to an offspring in the form of colostrum or milk in an analogous art for the purpose of conferring passive immune protection against infection in new born mammals against E.coli O157.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the method of Dougan to generate anti-intimin antibodies in a host, and administer the generated anti-intimin antibodies to a new born offspring in the form of colostrum or milk as taught by Childlow, because Childlow teaches that through generating anti-E.coli O157 antigen antibodies to an appropriate antigenic material, in the mother (host), the administered colostrum and milk (see col. 1, line 56) results in unexpectly high titers of antibodies, with a corresponding reduced susceptibility to infection through passive immunization of the newborn.

The person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining passive immune protection in a new born offspring using anti-intimin antibodies generated to purified intimin as taught by Dougan, in the method of Childlow, because Dougan teaches the domain of intimin that mediates adherence to mammalian cells and antibodies generated to this domain of intimin would block binding to mammalian cells resulting in inhibition of colonization caused by enterohemorrhagic E.coli.

In the absence of a showing of unexpected results, Dougan in view of Childlow obviates the now claimed invention.

Conclusion

18. This is a non-final action

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

20. deAzavedo was cited previously to show that the C-terminal region of the attaching and effacing protein of EHEC is key to the process of binding to host patient receptors to cause infection and teaches that this domain carries the epitopes recognized by neutralizing monoclonal antibodies.

21. The reference to Alice Campbell (1991, page 3, section 1.2.1) is being made of record to show that polyclonal antibodies, while readily made, vary in specificity, type, and concentration of the antibodies generated.

22.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
August 8, 2001

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